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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,179	03/27/2002	Nobuaki Yatsuka	0230-0174P	3270
2292	7590	07/23/2004	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			MAIER, LEIGH C	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,179	YATSUKA ET AL.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 8-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,8,11,13 and 15-19 is/are rejected.
- 7) ☐ Claim(s) 9,10,12 and 14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1, 8, 13, and 17 have been amended. Claims 18 and 19 have been newly added. Claim 1 and 8-19 are pending. Any objection or rejection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 1, 8, 11, 13, 15, and 17 are again rejected as set forth in the previous Office action under 35 U.S.C. 102(b) as being anticipated by SCOTT (EP 295092). Newly added claims 18 and 19 are included in this rejection.

Applicant's arguments filed May 11, 2004 have been fully considered but they are not persuasive.

It is noted that the claims have been amended so that no specific condition has been recited in the "prevention" claims. They recite prevention of a disease caused by excessive sebum production and prevention of an oily skin condition.

Applicant contends that in method of use claims, a new method of use claim cannot be inherently anticipated unless the use is specifically recognized by the reference. First of all, if the use were recognized in the reference, the examiner would not rely on an inherency argument. In this case, the art describes the administration of HA fragments for the treatment of baldness. By Applicant's definition, treating baldness by administration of HA fragments must necessarily comprise inhibition of excessive sebum production.

Art Unit: 1623

The instant claims are recited in terms of the mechanism by which the product works, but the prior administration anticipates the claims. See MPEP 2112.02.

Claim Rejections - 35 USC § 103

Claims 1, 8, 11, 13, and 15-17 are again rejected under 35 U.S.C. 103(a) as being unpatentable over SCOTT (EP 295092), as set forth in the previous Office action. Newly added claims 18 and 19 are included in this rejection.

Applicant's arguments filed May 11, 2004 have been fully considered but they are not persuasive.

Applicant contends "the treatment of alopecia and the stimulation of hair growth are different disorders. [sic]" It appears that Applicant's position is that alopecia and baldness are different disorders. This statement is set forth with no further explanation. Neither is there any more specific differentiation between alopecia and baldness in the specification. Absent any more specific definition, the examiner must rely on the plain meaning of the words recited in the claims. See entry for "alopecia" from *Webster's New World Dictionary*.

Allowable Subject Matter

Claims 9, 10, 12 and 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. SCOTT teaches as set forth in the previous Office action. The reference is silent regarding the inhibition of sebum production. Therefore, one of ordinary skill would not be motivated to use the disclosed

Art Unit: 1623

product for any disorder, other than those explicitly disclosed, associated with excessive sebum production.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1623

Examiner's hours, phone & fax numbers

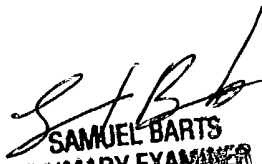
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0626. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Leigh C. Maier
Patent Examiner
July 19, 2004

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